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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,684	08/03/2001	Jorn Bullerdiek	BOH6277P0001	6746

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EXAMINER	
LIETO, LOUIS D	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,684	BULLERDIEK, JORN	
	Examiner	Art Unit	
	Louis D. Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-85* is/are pending in the application.

4a) Of the above claim(s) *62,63,72 and 74-85* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-61,64-71 and 73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 August 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/08/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the Restriction requirement was received on 4/09/2006. Claims 48-85 are pending in the instant application. Applicant's election with traverse of Group I, claims 48-61, 64-71 and 73, drawn to use of a preparation which contains an antiviral vaccine to produce a medicament for preventing and/or treating mesenchymal tissue changes, wherein at least one cell of said tissue is infected with a virus, and leiomyoma as the species of tissue change, is acknowledged.

Claims 62, 63, 72 and 74-85 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/09/2006.

Response to Arguments

Applicant's election with traverse of Group I in the reply filed on 4/09/2006 is acknowledged. However, Applicant did not present any grounds for traversal. This is not found persuasive because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claims 48-61, 64-71 and 73 are currently under consideration.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), the papers have been placed of record in the file.

Information Disclosure Statement

The references submitted on 08/01/2003 have been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO/SB/08A and 08B form, must be filed within the set period for reply to this Office action. Further it is noted that only the abstract of many of the references of 08/01/2003 were submitted. These references were only considered on the basis of the submitted abstract.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: For example, see Figures 2, part 1-part 4; Figures 3a(a) part 1- Fig. 3c(b); and Figures 4a part 1-Fig. 4a part 2. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not

accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the histological details as described in the specification. Specifically, the resolution and clarity of figure 6 is so poor as to make it impossible to clearly discern the PCR fragments on the gel. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 53 is objected to because of the following informalities: The word site is misspelled "sit", see line 1. Appropriate correction is required.

Claims 53-61, 64-71 and 73 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 53-55 depend from canceled claim 4. Since the subject matter of this claim was cancelled it is not possible to determine what subject matter applicant has claimed. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Accordingly, the claims 53-61, 64-71 and 73 have not been further treated on the merits.

Claims 56-61, 64-71 and 73 are objected to under 37 CFR 1.75(c) as being in improper form because they are multiple dependent claims that depend from prior multiple dependent claims. See MPEP § 608.01(n). Accordingly, the claims 56-61, 64-71 and 73 have not been further treated on the merits.

Claims 48, 49 and 52 are objected to because of the following informalities: The preamble of the claim is drawn to "a medicament for preventing and/or treating tissues changes". However the body of the claim states "wherein the tissue change involves tissue of mesenchymal origin." The claim is internally inconsistent, sine the phrase "tissue changes" is a genus, while a tissue change refers to a single species. Further, the specification only describes using the preparation to treat a tissue change involving tissue of mesenchymal origin (Specification, pg. 1, pgph 1). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51 and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 51 and 52 are drawn to a virus the nucleic acid of which contains at least one binding site for a gene product of genes of the HMGI(Y) family or derivatives thereof, and a virus the nucleic acid of which codes for a gene product and this gene product interacts with at least one gene product of genes of the HMGI(Y) family or derivatives thereof, respectively. These claims encompass a vast genus of gene products of genes of the HMGI(Y) family or derivatives thereof. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The specification contemplates gene products of genes of the HMGI(Y) family or derivatives, but does not define what sequences or functional domains of the receptor(s) are required for the derivatives to retain normal function.

The characteristics of the claimed genus contemplated in the specification are quite broad and include all " gene product of genes of the HMGI(Y) family or derivatives thereof." (pg. 3, pgph 5). This definition includes any gene product with any relation to the HMGI(Y) family, such as sharing a single base pair or amino acid in common.

The factors to be considered when assessing possession of the claimed invention include disclosure of complete or partial structure, physical and/ or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is the requirement that the nucleic acid sequence to be administered inhibit angiogenesis. The specification does not contemplate any specific functionally equivalent derivative thereof of the HMGI(Y) family. The specification only describes the HMGI(Y) family members, such as HMGIC or HMGIY (pg. 43, Ex. 2). Further the specification fails to identify any structural feature or functional element, common to all derivatives thereof of the HMGI(Y) family. It is suggested that removing language referring to "derivatives thereof" from the claims would be remedial. Accordingly, in the absence of sufficient recitation of a distinguishing identifying characteristic, the specification does not provide adequate written description of the claimed genus of gene products of genes of the HMGI(Y) family or derivatives thereof.

The Revised Interim Guidelines state, "when there is substantial variation with the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus" (Column 2, page 71436, or the Revised Interim Guidelines for Written Description). Case law concurs, stating, "simply describing large genus of compounds is not sufficient to satisfy written description requirement as to particular species or sub-genus" *Fujikawa v. Wattanasin*, 39 USPQ2d 1895 (CA FC 1996). Furthermore, *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled the art that, as of the filing date sought, he or she

was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Thus, the specification does not meet the written description provision of 35 U.S.C. 112, first paragraph, for a genus of gene products of genes of the HMGI(Y) family or derivatives thereof. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48-52 provide for the use of a preparation, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 48-52 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

In the interests of compact prosecution it is noted that claims 61, 64-71 and 73 are also drawn as use claims and if amended solely to correct their dependency problems will be rejected in any future office action as use claims, under the above statutes.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

It is noted that because the claims are constructed as use claims it is unclear as to what the claimed invention is. However, for the purposes of examination the claims have been interpreted as a method of making a medicament with a preparation that contains an antiviral agent. Applicant should note that intended use is not given patentable weight in claims that define a structure with functional language that reads solely on intended use. "When the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent." See MPEP 2112.01 or In re Best, 195 USPQ 430, 433 (CCPA 1997). It is noted that the use of a product for a particular purpose is not afforded patentable weight in a product claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand-alone. The MPEP states that,".. in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." In re Casey, 152 USPQ 235 (CCPA 1967); In re Otto , 136 USPQ 458, 459 (CCPA 1963)(MPEP 2111.02).

Claims 48-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Breinig et al. (1982) J. Interferon Res. 2:195-207.

Breinig et al. provides guidance on a method of making a medicament containing the antiviral agent interferon alpha for use in treating warts caused by the herpes simplex virus. Specifically, Breinig et al. teaches that a preparation of lyophilized human leukocyte interferon alpha was reconstituted 10^7 unites/ml to make a medicament for administration by intramuscular injection (Abstract; Materials and Methods, pg. 196-197). Interferon alpha is an antiviral agent that is inherently effective against herpes viruses, such as herpes simplex 1 (HSV-1). For example see, Chatterjee et al., who teaches that interferon alpha blocks the release of herpes simplex viruses, such as HSV-1, and inhibits the release of particles from infected cells {Chatterjee et al. (1985) J. Virology 56: 419-425; Abstract; pg. 420, Fig.1; pg.422 Fig. 3; pg. 424, Fig. 5}. HSV-1 inherently contains a binding site for a HMGI(Y) protein. For example see, French et al., who teaches that HMGI(Y) binds to the LAP2 promoter of the herpes virus HSV-1. {French et al. (1996) Mol. & Cell Biol. 16:5393-5399; Abstract, pg. 5394, Fig. 1; pg. 5396, Figs 6&7; pg. 5397, Fig. 8}. Further, herpes viruses inherently encode proteins that can interact with HMGI(Y) proteins. For example see Bullerdiek J., who teaches that the transforming viral proteins interact with the HMGI(Y) proteins to address the same promoters of genes in host cells {Bullerdiek J. (1999) Genes, Chromosomes & Cancer 26:181-183.pg. 181, pgph 4}. Thus, by teaching all the limitations of the claims as written, Breinig et al. anticipates the instant invention as claimed.

No claims allowed.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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